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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,288	01/14/2004	Yaron Keidar	BIO-173-CIP	4500

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,288

Applicant(s)

KEIDAR, YARON

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 27-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 and 27-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/25/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Applicant's amendments and comments, received June 19, 2006, have been fully considered by the examiner. The following is a complete response to the June 19, 2006 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25 and 27-48 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Independent claims 25 and 40 have been amended to recite a probe "which is inserted into the body so as to contact tissue". This language is a positive recitation of tissue, which is improper and non-statutory. Applicant's previous language "a probe, which is adapted to be inserted into the body" is the proper language for reciting an intended use of the probe without positively reciting the non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25 and 27-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are unclear with the positive recitation of non-statutory tissue (see previous 35 USC 101 rejection).

Claim Rejections - 35 USC § 103

Claims 25, 27, 28 and 30-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittman, III et al (6,575,969) in view of the teaching of Ben-Haim et al (6,690,963).

Rittman, III et al disclose a system and method for ablating and imaging tissue. With regard to the apparatus (applicant's claims 25-48), the Rittman system includes a probe (Figure 1) which is adapted to be inserted into tissue. The probe itself may act as a sensor and used in conjunction with CT, MR, ultrasound and acoustic imaging to measure one or more local parameters and provide an image of the probe within the tissue. Additionally, the probe may be provide with thermal sensors for sensing local parameters in tissue (see Abstract and col. 12, lines 12-43). Rittman discloses an ablative device for providing a set dosage of energy, a display to show a map of the tissue being treated and a controller for generating images including predicted and actual ablation profiles (see Figure 6 and column 14). In particular, column 14, lines 9+ discusses that the image data may be fed into the computer system and used to represent the system in various ways, including displaying calculated outcomes based on tissue and energy levels for preplanning the settings as well as overlaid models to show the comparative pre-planned view with the actual ablated tissue image. The computer controls the delivery of energy based on input parameters such as temperature and image data (see col. 13). It is noted that applicant's apparatus claims

are replete with recitation of elements “adapted” to perform various functions. The examiner maintains that the imaging and control system disclosed by Rittman is inherently capable of (i.e. “adapted to”) performing the functions. Additionally and with respect to the method claims, Rittman specifically disclose the performance of these various steps, including providing a mapping imaging prior to ablation, providing an image of a predicted extent of the ablation profile, and providing an image of the actual ablation profile in comparison with the predicted profile image (col. 14). The only feature not expressly disclosed by Rittman, III et al is a position sensor for generating signals to determine the position and orientation of the probe during use.

Ben-Haim et al disclose a system for determining the location and orientation of a probe within the body, much like the Rittman et al system. In particular, Ben-Haim et al teach that the probe may be provided with sensor coils (Figure 2) to assist in determining the location and orientation of the device during imaging. The examiner maintains that one of ordinary skill in the art would recognize that any known alternative location means, such as taught by Ben-Haim et al, may be used when identifying the location of a medical probe. Use of that information to determine the predicted profiles in the Rittman, III et al system would be an obvious, if not inherent, use of the information.

To have provided the Rittman, III et al system with sensor coils on the probe device to provide information regarding the location and orientation of the device within tissue during imaging would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Ben-Haim et al.

Claims 1-3, 6-14, 16, 17, 19-23, 25-40 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (2003/0109871) in view of the teachings of Rittman, III et al (6,575,969) and Ben Haim et al (6,690,963).

Johnson et al disclose a system and method for treating tissue comprising a probe (12) that is brought into contact with tissue, the probe having sensors for measuring one or more local parameters (e.g. impedance) of tissue in order to display a map of the tissue. Paragraph [0102] of the Johnson et al device addresses the use of mapping to show pre and post-surgical mapping of tissue during an ablation procedure using the sensors. Further, paragraph [0100] discloses the use of the sensors and mapping to control the delivery of ablation energy. Johnson et al fully disclose all the necessary display and control means for viewing, mapping and controlling the delivery of energy during the procedure. However, Johnson et al fail to specifically disclose a means to display a map of the predicted ablation of tissue for a given applied dosage, as well as means to display the actual ablation in comparison to the predicted model. Johnson et al also fail to disclose the particular position sensor means for generating signals to determine the position and orientation of the probe.

Rittman, III et al, as addressed previously, disclose an analogous RF system for treating tumors. In particular, the Rittman system includes the same basic RF probe, imaging and mapping system as set forth in the Johnson et al system. Rittman specifically teach that it is advantageous to provide predicted ablation mapping based

on an applied dosage which can be compared to actual ablation images to predict and control the ablation of tissue (column 14).

Also addressed previously, Ben-Haim et al disclose the known use of position sensor coils to generate signals used to determine the position and orientation of a medical probe and/or catheter.

To have provided the Johnson et al system with a means to display a predicted ablation model to estimate the amount of tissue damage resultant from a given dosage would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Rittman, III et al. To have further provided the Johnson et al system with a position sensor means for determining the precise position and orientation of the probe during treatment would have been an obvious consideration for one of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed June 19, 2006 have been fully considered but they are not persuasive.

Independent claims 25 and 40 have been amended to include recitation of a position sensor for generating signals and determining the position and orientation of the probe, and a controller which uses this information in generating the predicted ablation profile.

Rittman discloses various imaging means for determining the position and location of the probe within the body. The location of the device is used to create a predicted ablation profile and to compare the actual ablation with the predicted ablation

profile as addressed in this and the previous Office action. The examiner maintains that the use of any known positioning means to precisely determine the location of the device within the body, as is necessary for the device, would be an obvious design consideration for one of ordinary skill in the art. Ben-Haim et al teach that it is known to use a position sensor including coils as an alternative to ultrasonic and fluoroscopic imaging.

Applicant asserts that Rittman fails to disclose the particular position sensor as now set forth in the claims. The examiner agrees. However, the applicant contends on page 11 of the response that there is no objective evidence that can be found that would indicate why the teachings of Ben-Haim et al, Rittman III et al and Johnson et al may be combined. Applicant continues to make the broad statement that the divergent teachings of these references provide no incentive to modify the teachings to lead to applicant's invention. The examiner disagrees with these arguments.

As asserted in the rejections, Rittman clearly provides a probe and controller system for creating a predicted ablation profile for comparison with the actual ablation procedure. Rittman uses an imaging means for locating the probe and creating the predicted profile. Rittman simply does not teach the specific positioning means including a position sensor to generate a signal for determining position and orientation of the probe in tissue. Rather, Rittman disclose the use of CT, MRI or other imaging means to locate the probe in tissue. Ben-Haim et al disclose an alternative imaging means including a position sensor located in the probe, the position sensor creating signals that are used to determine the position and orientation of a medical device in

tissue. Such an imaging means is an alternative to other known imaging systems such as CT, MRI and ultrasonic imaging. The examiner maintains that there is clear motivation and suggestion to one of ordinary skill in the art to use the alternative positioning means taught by Ben-Haim et al in the Rittman system for determining the precise location of the probe in the tissue being treated.

Applicant has not specifically addressed the Johnson et al device other than to assert it did not have the position sensor means as now set forth in the claims. The examiner agrees, but maintains that it would have been obvious to use the positioning means taught by Ben-Haim et al to precisely locate the probe within the tissue being treated. As asserted in the above rejection and the rejection of the previous Office action, the examiner maintains that it would be further obvious to use the predicted modeling controller as taught by Rittman to provide predicted and real-time data on a display to guide a user through the procedure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

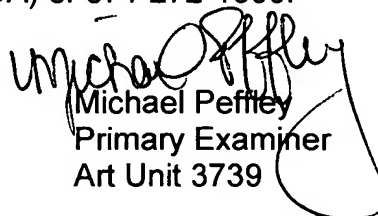
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

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